

II. REMARKS

Preliminary Remarks

Reconsideration based on the following remarks are respectfully requested. Claims 1-26 are currently pending in the application. Claims 7-14 and 26 were withdrawn from consideration. Claims 1-6 and 15-25 are currently at issue.

This response is timely filed as it is accompanied by a petition for an extension of time to file in the first month (extended) and the requisite fee.

Claims 7-14 and 26 were objected to under 37 C.F.R. §1.75(c) as being in an improper form because these multiple dependent claims depend upon other multiple dependent claims. Claims 6, 7, 10 and 11 have been amended to remove the improper multiple dependencies. Therefore, the applicants request the withdrawal of this objection.

The examiner also objected to pending claims 20 and 21 for use of the phrase “any one of” and has suggested deleting this phrase. The applicants have amended claims 20 and 21 removing the phrase “any one of” as suggested by the examiner. Therefore, the applicants request the withdrawal of this objection.

Claims 3, 17 and 25 have been canceled without prejudice. Aspects of each claim have been applied to claims 1 and 15. Claim 1 has been amended to be directed to a bone implant having a surface comprising a bioactive material wherein the (a) bioactive material has incorporated therein ions from one or more of the groups of the periodic table consisting of groups IIA, IVA, VIIA and transition elements; (b) the ions are incorporated into or onto the surface of the bone implant up to a maximum depth of 200 nm; and (c) the bioactive material is a material that is capable of promoting bone growth onto the bone implant. Support for amended claim 1 is found throughout the specification, for example, originally filed claims 1 and 3.

Claim 15 has been amended to be directed to a method of treating a bone implant having a surface comprising a bioactive material to improve the bone ongrowth properties of the bone implant comprising subjecting the bone implant to ion beam embedding thereby to incorporate ions into the surface up to a maximum depth of 200 nm from one or more of the groups of the periodic table consisting of groups IIA, IVA, VIIA and transition elements into

the surface. Support for amended claim 15 is found throughout the specification, for example, in originally filed claims 15 and 17.

The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

Patentability Remarks

Rejection Pursuant to 35 U.S.C. § 112, second paragraph

On page 2 of the official action, claims 1-6 and 25 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicants regard as the invention. Specifically, the examiner rejected claims 1 and 25 for the recitation of the phrase “the ions are incorporated into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition.” The examiner alleged this phrase is indefinite for the general rule that if the structure is described by the process of making rather than in structural terms and the structure is capable of description in structural terms, it should be described in structural terms. In addition, the examiner further rejected claim 25 for the recitation of “the surface atomic layers” because it lacked prior antecedent basis.

The applicants believe that the maximum dept of ion incorporation in amended claim 1 and claim 25 is a structural feature **that results** from the methods of ion beam implantation or cathodic arc deposition. Therefore, it is the applicants’ position that the structure is **not** described by the process. Nevertheless, in order to expedite prosecution and without prejudice to the applicants’ right to seek broader claims in a continuing application, claim 25 has been canceled without prejudice thereby obviating the rejections of this claim. Further, claim 1 has been amended to be directed to a bone implant having a surface comprising a bioactive material wherein the bioactive material has incorporated therein ions from one or more of the groups of the periodic table consisting of groups IIA, IVA, VIIA, and transition elements; the ions are incorporated into or onto the surface of the bone implant up to a maximum dept of 200 nm; and the bioactive material is a material that is capable of promoting bone growth onto the bone implant. Support for amended claim 1 can be found throughout the specification, for example, originally filed claims 1 and 3.

In view of the foregoing amendment and remarks, the rejections of claims 1 and 25 under 35 U.S.C. §112, second paragraph, based on the examiner's allegation have been overcome and should be withdrawn.

Rejections Pursuant to 35 U.S.C. §102, Anticipation

35 U.S.C. §102(b), U.S. Patent Number 5,164,187

On pages 3 and 4 of the official action, the examiner maintained his rejection of claims 1 and 2 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,164,187 (hereafter "Constantz"). Specifically, the examiner alleged that Constantz appears to be substantially identical to the device claimed because the method of forming the device (*i.e.*, the ion beam implantation or cathodic arc deposition) is not germane to the issue of patentability of the device itself. Therefore, the examiner concluded no patentable weight has been given to the limitation. The applicants respectfully traverse this rejection.

As discussed above, the applicants have amended part (b) of claim 1 to contain the feature of ions that are incorporated into or onto the surface of the bone implant up to a maximum depth of 200 nm. As acknowledged by the examiner on page 5 of the office action, Constantz does not incorporate the feature that ions are incorporated into the surface up to a maximum depth of 200 nm. Claim 2 by its dependency from claim 1 also maintains this feature as well. Accordingly, the applicants respectfully submit the rejection of claims 1 and 2 under 35 U.S.C. §102(b) is overcome and should be withdrawn.

35 U.S.C. §102(e), U.S. Patent Number 5,817,326

On page 4 of the official action, the examiner rejected claims 1, 2, 15, 16, and 21-24 under 35 U.S.C. §102(e) as allegedly being anticipated by Nastasi *et al.* (U.S. Patent No. 5,817,326) (hereafter Nastasi). Specifically, the examiner alleged that Nastasi discloses an implant having a hydroxyapatite coating that is incorporated with ions selected from the chemical groups IIA, IVA, VIIA, and transition elements. The examiner further alleged that these ions are incorporated by an ion beam implantation process. The examiner asserted the method of claim 1 (*i.e.* ion beam implantation or cathodic arc deposition) was not germane to the issue of patentability of the device itself and therefore has not been given patentable weight even though Nastasi disclosed the ion incorporation method of ion beam implantation.

Claim 15 has been amended to be directed to a method of treating a bone implant having a surface comprising a bioactive material to improve the bone ongrowth properties of the bone implant comprising subjecting the bone implant to ion beam embedding thereby to incorporate ions into the surface up to a maximum depth of 200 nm from one or more groups of the periodic table consisting of groups IIA, IVA, VIIA and transition elements into the surface. As discussed above, claim 1 also incorporates the 200 nm depth requirement as well. As acknowledged by the examiner on page 6 of the office action, Nastasi does not incorporate the feature that ions are incorporated into the surface up to a maximum depth of 200 nm. Claims 2, 16, and 21-24 are either directly or indirectly dependent upon either claims 1 and 15 and therefore also maintain the 200 nm depth requirement. Accordingly, the applicants respectfully submit the rejection of claims 1, 2, 15, 16, and 21-24 under 35 U.S.C. §102(b) is overcome and should be withdrawn.

Rejection Pursuant to 35 U.S.C. § 103(a), Obviousness

35 U.S.C. §103, Constantz

On page 5 of the official action, the examiner rejected claims 3-6, and 25 under 35 U.S.C. §103(a) as being unpatentable over Constantz. Specifically, the examiner alleged Constantz discloses the claimed invention except for the ions being incorporated on to the surface of the implant up to a maximum depth of 200 nm (claims 3 and 25), or up to a maximum depth of 150 nm (claim 4), or up to a maximum depth ranging up to approximately 100 nm (claim 5), or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface (claim 6). The examiner concluded it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant disclosed by Constantz with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, 150 nm or 100 nm, or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art where the general conditions of a claim are disclosed in the prior art.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or reference when combined) must teach or suggest all the

claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The examiner bears the burden of establishing a prima facie case of obviousness and "can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fine*, 5 U.S.P.Q.2d 1598 (Fed. Cir. 1988). To support a conclusion that a claimed composition is obvious, either: (a) the references must expressly or impliedly suggest the claimed composition to one of ordinary skill in the art, or (b) the examiner must present a convincing line of reasoning as to why a person of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Inter. 1985).

The applicants submit that Constantz neither teaches or suggests all the claim limitations of applicants' claimed invention, *i.e.*, a bone implant having a surface comprising a bioactive material wherein the bioactive material has incorporated therein ions from one or more of the groups of the periodic table consisting of groups IIA, IVA, VIIA, and transition elements; the ions are incorporated into or onto the surface of the bone implant up to a maximum dept of 200 nm; and the bioactive material is a material that is capable of promoting bone growth onto the bone implant.

Specifically, the applicants respectfully submit that the examiner specifically alleged Constantz teaches an implant having a hydroxyapatite coating that can have incorporated therein a variety of ions. In this regard, Constantz describes a method in which soluble sources of calcium and phosphate are combined under controlled conditions of nucleation and growth with the end result of forming uniform coatings, on porous structures for bone ingrowth. The examiner has previously pointed out that Constantz refers to "substitution" of calcium cations with other ions (column 2, lines 52 and 53). The applicants do not disclose the method by which "substitution" of the calcium ions is achieved.

① If it is assumed that substitution is effected by replacing the calcium source during nucleation and crystal growth with a source in which the calcium ion is substituted, then the maximum ion depth will effectively be the depth of the resulting coating. In this regard, column 2, lines 39 to 43 of Constantz states that the hydroxyapatite coating may be as thin as

about 2 μm , and more preferably at least about 10 μm , and may range to 40 μm thick or greater. Furthermore, lines 50 to 54 of column 2 of Constantz states that the phosphate and hydroxy ions may be substituted with other ions.

Accordingly, taking the maximum depth of ion incorporation in the implant of Constantz to be dictated by the thickness of the coating itself, the above passages, at most, disclose a coating with ions incorporated up to a maximum depth of between 2000 nm and at least 40,000 nm. Thus, since 2000 nm is ten fold higher than the maximum depth disclosed in amended claim 1 (200 nm) and since this is the lowest depth that can be considered from the teaching of column 2, the subject matter of amended claim 1 would not be obvious from Constantz.

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The applicants also refer to column 3, line 22 of Constantz, which states that the method involves applying at least two layers. The first layer is stated to be of a thickness in the range of 0.01 μm to 20 μm , and the second coating to be of a thickness in the range of 1 μm to 40 μm . This implies a minimal total thickness of between 1010 nm to 60,000 nm, which again is significantly higher than the depth disclosed in amended claim 1. These levels are minimum depths since Constantz advocates the application of one or more additional coating (column 3, lines 30-34). In this regard, Constantz states that the total thickness of the second and succeeding layers will generally be in the range of 5 μm to 20 μm .

Opponent to which disclosure is directed

The applicants submit their invention is directed to a maximum ion depth of 200 nm recited in the present application. This disclosed ion depth actually achieves an unexpected enhancement of bone formation onto the substrate without affecting the mechanical and surface properties of the implant surface at ion depths up to a 1000 fold less than those taught in Constantz (see page 3, lines 29 to page 4, line 8). The depth is a consequence of using the techniques of ion beam implantation or cathodic arc deposition. Accordingly, this ion depth would not be possible, let alone a routine optimization of the teaching of Constantz, which does not disclose or suggest these techniques. Constantz implies that there is a limit to the relatively thin coatings that must be employed to avoid thick brittle ceramic interfaces between the substrate and the ductile bone because Constantz does not refer to the ion substitutions in the context of improving or enhancing bone on-growth onto an already established layer. Instead, Constantz states that "these substitutions will influence the *in vivo* dissolution behavior of the coating." [See column 2, lines 39-54]

In summary, the applicants submit that Constantz neither teaches nor suggests the applicants' claimed invention. Accordingly, without such teaching or suggestion, the examiner has not established a *prima facie* case of obviousness, therefore, withdrawal of the rejection based on 35 U.S.C. §103(a) is respectfully requested.

35 U.S.C. §103, Nastasi

On page 6 of the official action, the examiner rejected claims 3-6, 17-20, and 25 under 35 U.S.C. §103(a) as being unpatentable over Nastasi. As with Constantz, the examiner alleged that it would have been obvious to one having ordinary skill in the art at the time the invention by Nastasi to incorporate ions into the surface of the implant up to a maximum depth of 200 nm, or up to a maximum depth of 150 nm, or up to a maximum depth range of 100 nm, or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface, since it has been held that where the general conditions of claims are disclosed by the prior art, discovering the optimum or workable ranges involves only routine skill. Again, the applicants traverse respectfully submitting their teachings are from the "optimum or workable ranges" conceived by Nastasi.

The applicants submit that Nastasi neither teaches or suggests all the claim limitations of applicants' claimed invention, *i.e.*, a method of treating a bone implant or a bone implant having a surface comprising a bioactive material wherein the bioactive material has incorporated therein ions from one or more of the groups of the periodic table consisting of groups IIA, IVA, VIIA, and transition elements; the ions are incorporated into or onto the surface of the bone implant up to a maximum dept of 200 nm; and the bioactive material is a material that is capable of promoting bone growth onto the bone implant.

Specifically, Nastasi provides a method of making a bone implant in which a first sol-gel layer is densified and hardened by non-line-of sight ion beam implantation using argon to provide mixing of titanium and hydroxylapatite. However, column 5 of Nastasi *et al.* states that "subsequent layers are added to provide a gentle density gradient...with the outermost (lower density) layers permitting bone ingrowth; the final layered prosthesis providing greater strength than those presently available". Nastasi *et al.* then goes on to state that "the total coating thickness would optimally be between 50 and 200 μm ." [See Nastasi, column 5, lines 5-10]

In view of the above statement, the ions incorporated into the hydroxylapatite in Nastasi are actually present in the resulting bone implant at a depth of between at least 50 and 200 μm (*i.e.*, between at least 50,000 and 200,000 nm), which is in stark contrast to maximum depth of 200 nm recited in the present application. Furthermore, the above passage emphasizes that Nastasi considers the bone implant having a total coating thickness of between 50 and 200 μm to be "optimized," and that such a feature is essential to the operation of the bone implant (permitting bone ingrowth and providing greater strength).
Accordingly, it would be far from obvious for the skilled person to modify this teaching to arrive at the present invention.


Indeed, the difference in ion depth between Nastasi and that of the present invention is borne out by the different problems addressed by Nastasi and the present invention. In this regard, the applicants utilize the incorporation of ions into the surface of the bone implant to enhance bone ongrowth into the established layer. In contrast, Nastasi incorporates argon into the hydroxyapatite to improve the bonding of the first sol-gel layer to the titanium substrate, and relies on the subsequent application of non-substituted layers to permit bone ongrowth.

Accordingly, the applicants submit that Nastasi neither teaches nor suggests the applicants' claimed invention. Accordingly, without such teaching or suggestion, the examiner has not established a *prima facie* case of obviousness. Therefore, withdrawal of the rejection based on 35 U.S.C. §103(a) is respectfully requested.

III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue which the examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

All objections and rejections have been addressed, it is respectfully submitted that the present application is in a condition for allowance and a notice to that effect is earnestly solicited.

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